

RESPONSE TO RESTRICTION REQUIREMENT	Application #	10/527,422
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	First Inventor	BARTOSCH
	Art Unit	1633
	Examiner	Popa, Ileana
	Docket #	P08575US00/BAS

Commissioner for Patents
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S I R:

In response to the Restriction Requirement dated March 17, 2008, Applicants submit the following election response, with traverse.

In the Restriction Requirement dated March 17, 2008, the Examiner has alleged that the present application includes claims drawn to one of five inventions, Groups I-V, corresponding to:

Group I, claims 46-70 and 82-87, drawing to a method of producing infectious hepacivirus-like particles *ex vivo*;

Group II, claim 71, drawn to a method of producing infectious hepacivirus-like particles *in vivo*;

Group III, claims 75-77 and 90, drawn to a method of *ex vivo* identification of a hepacivirus receptor by detecting the binding of an infectious virus to a cell receptor;

Group IV, claims 78, 88 and 89, drawn to a method of *ex vivo* screening for molecules interfering with the hepacivirus entry into cells; and

Group V, claims 79-81, drawn to a method of *in vitro* diagnosis of a hepacivirus infection in a patient.

In addition, the Examiner has required an election of species should Applicants select the claims of Group I, with traverse.

In response to the Restriction, Applicants respectfully select Group I, claims 46-70 and 82-87, and elect the native E2 species of claims 52, 53 and 64.

Turning to the Restriction Requirement in detail, in alleging that the application includes more than a single invention, the Examiner alleges that Groups I-XI [sic] do not relate to a single general inventive concept, alleging that either:

A) The invention has no special technical feature that defined the contribution over the prior art, or

B) Unity of invention between different categories of inventions are lacking.

Contrary to the Restriction, Applicants respectfully submit that the present application is directed to a single general inventive concept, namely the production of an infectious hepatitis virus-like particle having mutated E2 proteins, as claimed.

Applicants respectfully submit that the novel subject matter recited in Group I is also recited in Groups II-V. Specifically, the elected Group I and selected species, native E2 protein, as recited in claims 52, 53 and 64, include subject matter in which mutated E2 protein is either an E2 protein deleted from its C-terminal amino-acid residue and a native E2 protein, wherein the hypervariable region 1 (HRV1) has been deleted. The E2 protein deleted from its C-terminal amino-acid residue differs from full length E2 protein only by the last amino-acid residue. Therefore, the sequence of the mutated E2 protein is encompassed in the sequence of the whole native E2 protein, thus differing by the addition of a single amino-acid residue. Accordingly, searching for the whole protein native E2 protein necessarily results in searching for the one amino-acid truncated mutated E2 protein of claims 57 and 67.

Further, the HRV1 domain is clearly identified (see, e.g., SEQ ID NO:16) and is composed of only 26 amino acids, whereas the sequence of the full-length E2 protein is composed of more than 360 amino acids. Therefore, a search of the E2 protein, wherein HRV1 is deleted, the sequence of which is about 93% identical to the sequence of the full-length E2 protein, should give similar results to a search performed on the full-length E2 protein. Accordingly, the field of search of these mutated proteins is the same or substantially identical to the native protein. Therefore, no undue burden or additional search is required in order to examine all claims.


Finally, the specification discloses that a 10 to 50 fold enhancement of infectiosity was observed with the HCV pseudo-particles harboring the C-terminally truncated E2 protein (see present specification, page 8, lines 33 and 34) and that hepacivirus pseudo-particles containing an E2 glycoprotein wherein HRV1 was deleted still remained infectious (see present specification, page 9, lines 8-10). Accordingly, the same prior art relating to the production of infectious hepacivirus-like particles is likely to be applicable to both species of native and mutated E2 proteins. Accordingly, there would be no undue burden or additional search required in order to consider all claims.

Finally, it should be emphasized that the International Preliminary Examining Authority, in issuing its International Preliminary Examination Report, did not find a lack of unity of invention (see the attached International Preliminary Examination Report, Part 3, Box IV, "Lack of unity of invention," which is not marked). Thus, the entity with expertise in determining whether an application lacks unity of invention has found that no such lack of unity of invention is present in the present application.

For the reasons set forth above, Applicants respectfully request withdrawal of the Restriction Requirement, and examination of the full set of claims in the present application is thus appreciated.

Respectfully submitted,

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